This proposed guidance reflects the current thinking on the use and purchase of facemasks and respirators by individuals and families for pandemic influenza preparedness. The information contained in this document is distributed solely for the purpose of pre-dissemination public comment. It has not been formally disseminated by HHS. It does not represent and should not be construed to represent any agency determination or policy.

Interim guidance on the use and purchase of facemasks and respirators by individuals and families for pandemic influenza preparedness

This document provides interim guidance for the use of respirators and facemasks by individuals and families during an influenza pandemic. It was developed from existing U.S. Department of Health and Human Services guidance for the use of these devices in non-occupational community settings, posted on the internet at http://www.pandemicflu.gov/plan/community/maskguidancecommunity.html. While we do not have sufficient data to make science-based recommendations regarding every aspect of facemask and respirator use, individuals and families have requested additional information to assist in their pandemic influenza preparedness plans.

During an influenza pandemic, one may become ill following close contact with someone who is infected at home, in the community, at work, or at school. The best ways to reduce the chance of illness are to avoid crowded settings, reduce close contact with others (within about 6 feet), and practice good hygiene (handwashing and covering coughs and sneezes). Using protective measures in workplaces, reducing contacts among children by closing schools, and canceling public gatherings also are likely to further reduce the risk of infection if these measures are used in the event of a severe pandemic. Facemasks and respirators may further decrease, but will not eliminate the chance of becoming infected, so their use does not lessen the importance of reducing close contacts and improving hygiene: the best protection can be achieved by combining several measures, each of which will partially protect against pandemic influenza.

A facemask or respirator, if used correctly, may reduce the risk of acquiring or transmitting pandemic influenza illness in certain situations. Although the actual benefit of facemasks or respirators in preventing influenza transmission is unknown, use in certain situations may be warranted during a pandemic. If entry into a crowded setting is unavoidable (e.g., mass transit or going to a crowded store to purchase essentials such as medications), a facemask should be used, both to protect the wearer's nose and mouth from other people's coughs and sneezes, and to reduce the wearer's likelihood of coughing or sneezing on others. A respirator should be used by individuals for whom close contact with an infectious person is unavoidable, such as when caring for a sick household member.

Key messages:

- 1. The first and most important steps in reducing one's risk of pandemic influenza are to limit close contact with others as much as possible and to practice good hygiene. These measures should be used at all times, regardless of whether a facemask or respirator is worn.
- 2. When a person cannot avoid being in a crowd during an influenza pandemic for example, because they must commute to work on public transit but has no specific expectation of encountering a sick person, they should use a facemask.

- 3. When it is necessary to have close contact with someone who is ill with pandemic influenza for example, to give care to a family member one should use an N95 respirator or equivalent certified by the National Institute of Occupational Health and Safety (NIOSH) and consider specifically using a respirator model that also is cleared by the U.S. Food and Drug Administration (FDA) for use by the general public in public health medical emergencies.
- 4. Ill persons should use a facemask when they must be in contact with others.

A facemask (for example, a surgical mask) is a disposable mask that covers the nose and mouth. When used properly, facemasks may help protect against influenza by blocking droplets – created when someone coughs or sneezes nearby – from reaching the wearer's nose or mouth. If someone who is infected with influenza wears a facemask, it will trap their own secretions and may help protect others who are nearby. A facemask also may help keep an uninfected wearer from touching their nose or mouth and potentially infecting themselves with influenza virus that is on their hands. Facemasks are inexpensive and are relatively comfortable to wear. Some small facemasks may fit larger children but children may have trouble wearing them correctly and consistently.

The FDA has cleared many facemasks. These facemasks have been tested to show that they can trap germs and resist fluids, and will not cause skin reactions or breathing difficulties. FDA-cleared facemasks are labeled to be used by healthcare professionals and generally marketed as medical products sold "over the counter" by medical supply companies. They may be labeled as surgical masks, procedure masks, isolation masks, dental masks, or laser masks. FDA has not cleared any facemasks specifically for use by children. Disposable masks that are not labeled for medical uses are not subject to FDA oversight and their quality is not known. Even if they look similar to facemasks, disposable masks not labeled for medical use, such as those commonly sold at hardware stores, may not provide the same protection against infection. Questions about a brand or type of facemask may be answered by a pharmacist or healthcare provider. General information on buying or wearing facemasks may be found on the FDA website, http://www.fda.gov/cdrh/ppe/masksrespirators.html. Instructions on how to correctly put on and take off a facemask are included with the packaging of some products. Correctly removing a facemask so that one is not exposed to contaminated mask surfaces is very important; good handwashing or use of a waterless hand-hygiene product before putting on and after taking off a facemask is critical.

An N95 filtering facepiece respirator is a disposable respirator that covers the nose and mouth. Like a facemask, a respirator will trap infected droplets. In addition, if worn correctly, it will protect against breathing in small particles that may contain viruses. Respirators, which generally are worn in healthcare and other occupational settings, are tested and certified by NIOSH. NIOSH-certified disposable N95 respirators are marked with the manufacturer's name, the part number (P/N), the level of protection provided by the filter (e.g. an N95 respirator is certified to filter out 95 percent of the most penetrating

particulates), and "NIOSH." Non-certified respirators are available but their effectiveness has not been tested by NIOSH. For questions about a brand or type of respirator, consult the NIOSH website, http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/. Instructions for correctly putting on and taking off a respirator are included in the package. As with facemasks, correctly removing and disposing of the respirator to avoid becoming infected from secretions that may be on the device is important; it is critical that hands be washed or decontaminated with a waterless hand-hygiene product before putting on and after taking off a respirator.

A respirator works by fitting snugly against the face, forcing inhaled air to come through the filtering material. In workplaces where most N95 respirators are used, they are "fit tested" to assure that air does not leak around the sides of the respirator. Although fit testing programs generally are not available for the public, selecting an appropriate respirator, carefully following instructions for its use, and making sure that it fits tightly against the face are critical to ensuring the respirator provides protection. Facial hair or other items that interfere with a close fit will diminish effectiveness. FDA recently cleared the first respirators specifically intended for use by the general public during a public health medical emergency such as a pandemic. These respirators, which also are NIOSH-certified, have directions that are written for untrained users and were tested to show that adult users with a variety of facial sizes could obtain a protective fit using those instructions. Their labeling instructions address the other precautions also needed for the safe use of respirators during an influenza pandemic such as handwashing, proper storage before use, and proper disposal after use. Where these are available, they may be the best option for users without access to fit testing. No respirator, however, will fit all users and one may want to purchase several sizes or models to see which fits best (i.e., fits snugly against the contours of the face) before purchasing a larger quantity. There are no respirators designed for use by children. Because the material used to make respirators is denser than that used in facemasks, it may be more difficult to breathe through a respirator. Persons who have heart or lung disease or other illnesses that affect their breathing should consult a healthcare provider before using a respirator.

The effectiveness of both facemasks and respirators is reduced after they are worn for a long time and become saturated with moisture, or if they are torn or disfigured. At such times, they should be replaced. They can also become less comfortable to wear and may be more difficult to breathe through after extended use. Because the best ways to prevent influenza infection are to avoid crowds and reduce close contacts with others, there should not be a need to wear facemasks and respirators for long periods of time. In addition the facemasks and respirators should be removed when the wearer is no longer in a setting where close contact will occur. Never wash or disinfect disposable facemasks or respirators and never share used facemasks or respirators with others.

¹ It is important to note that other NIOSH-certified N-, R-, or P- filtering facepiece respirators (e.g., N99, R95, and P100) provide an equal or greater level of exposure reduction to airborne particulates as an N95 and can be used if N95s are not available.

Settings where respirators and facemasks should be used will depend on the potential for exposure to infectious persons:

A facemask is recommended when exposure in a crowded setting occurs with persons not known to be ill. An example would be exposure on a crowded bus or subway while commuting to work during a pandemic. Because ill persons are advised to stay home during a pandemic, contacts in most public settings will be with persons who are not ill. However, it is prudent to wear a facemask because one may encounter people who are infectious but not yet ill.

 A facemask also is recommended for use by ill persons when they must be in close contact with others. The facemask will trap the wearer's secretions and reduce the risk to other persons. Close contact between ill persons and others should be limited as much as possible. However, such contact will occur when the ill person is being cared for at home or if they need to leave home to access medical care or manage other necessities. Ill persons do not need to wear a facemask when they are not in close contact with others

• A respirator is recommended for use in settings that involve close contact (less than about 6 feet) with someone who has known or suspected influenza illness. In non-occupational settings, the most common use for a respirator would be in a household where someone has influenza. One person should be responsible for taking care of the ill individual and that person should wear a respirator during those contacts. The Centers for Disease Control and Prevention (CDC) will be issuing guidance on home care of an ill person, which will be posted on the internet at www.pandemicflu.gov.

Families can use this guidance as the basis for making decisions about purchasing respirators and facemasks as part of household pandemic preparedness. Although not all households will have someone who becomes ill with influenza during a pandemic, because one cannot predict in which households an infection will occur, it would be reasonable for each household to stockpile some respirators that can be used, if needed, when caring for an ill family member. With proper precautions, a single caregiver can use the same respirator several times over a day for brief care visits with the same ill person in the household, so a stockpile of 20 respirators per household would be reasonable. Decisions on stockpiling facemasks and the number to obtain would depend on a family's situation and their expectation of the need for close contact in crowded settings during a pandemic. Pandemic outbreaks in communities may last 6 to 12 weeks. Persons who cannot avoid commuting on public transit may choose to purchase 100 facemasks for use when going to and from work. An additional supply of facemasks

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² If a respirator is used several times by a single caregiver for brief care visits with the same ill person, the outside of the respirator may become contaminated with secretions from the ill person; therefore care should be taken to keep the respirator away from other household members between uses and to wash hands well after putting the respirator on.

³In previous pandemics, community outbreaks generally have lasted 6 to 8 weeks. Effective public health measures to reduce the spread of infection in communities ("community mitigation") may reduce the overall severity of the pandemic outbreak but could lengthen its duration, potentially to 12 weeks.

also could be purchased for other times when exposure in a crowded setting is unavoidable or for use by an ill person in the home when they come in close contact with others.⁴ The cost of a box of 20 N95 respirators is about \$15 - \$30 and the cost of a box of 50 facemasks is about \$10 - \$20. Therefore, the total cost to a family to purchase the recommended number of respirators and facemasks would be about \$35 - \$70.

Because the supply of respirators and facemasks is limited, stockpiling only the amounts that may be useful during a pandemic and using them only when necessary will help assure that supplies are sufficient for all settings where they are needed: on a daily basis in healthcare and other workplace settings, and for pandemic preparedness among healthcare workers, emergency responders, and others who provide essential services in communities.

Stockpiling respirators and facemasks can contribute to pandemic preparedness in households but is not the only action that can be taken to prepare. Education on other measures to reduce the risk of being exposed and becoming ill, practicing good habits in handwashing and covering coughs and sneezes, as well as purchasing stockpiles of food and water all are recommended. Several scientific studies currently are being done to investigate the level of protection against influenza that may be provided by respirators and facemasks and the ability of persons to correctly and consistently use these devices. This interim guidance may be modified based on the results from these studies. Additional information on protecting oneself and one's family in a pandemic is available at http://www.pandemicflu.gov/plan/individual/index.html.

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⁴ Facemasks and respirators should be stored in a dry, cool location, and protected from moisture, insects, dirt and extremes of temperature.